

Gastrointestinal endoscopy services in Salvador, Bahia: analysis in the light of patient safety

Serviços de endoscopia gastrointestinal em Salvador, Bahia: análise à luz da segurança do paciente

Servicios de endoscopia gastrointestinal en Salvador, Bahia: análisis a la luz de la seguridad del paciente

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ABSTRACT: Objective: To analyze the incidence of adverse events related to gastrointestinal endoscopic procedures. **Method:** Multiple case study in Type III gastrointestinal endoscopy outpatient services, in the city of Salvador, Bahia, analyzing: Patient Safety Centers (*Núcleos de Segurança do Paciente* – NSP); adverse events and endoscopic decontamination. **Results:** 28.5% of the gastrointestinal endoscopy outpatient services in the city participated in the study. There are NSPs, which work according to Patient Safety Plans, but without a dedicated professional. Only one service monitors patients after endoscopy, which makes it difficult to identify adverse effects after procedures in these organizations. Basic patient safety protocols exist in most services. The total incidence of adverse effects is 0.3%; and 0.8% for upper digestive endoscopy and colonoscopies. Bacteremia, abdominal pain, bleeding, and intestinal perforation are the most frequent damages. All services have a good organofunctional structure for cleaning and disinfecting endoscopes. **Conclusion:** The services have NSPs and implement recommended safety protocols. The adverse effects identified are in line with the literature; however, these data may be underreported, since these services do not have an active surveillance system for adverse events after endoscopic examinations.

Keywords: Endoscopes. Patient safety. Adverse reactions.

RESUMO: Objetivo: Analisar a incidência de eventos adversos relacionados aos procedimentos endoscópicos gastrointestinais. **Método:** Estudo de casos múltiplos em serviços ambulatoriais de endoscopia gastrointestinal Tipo III, na cidade de Salvador, Bahia, analisando: Núcleos de Segurança do Paciente; eventos adversos e descontaminação dos endoscópicos. **Resultados:** Participaram 28,5% dos serviços ambulatoriais de endoscopia gastrointestinal da cidade estudada. Existem Núcleos de Segurança do Paciente, que atuam segundo Planos de Segurança do Paciente, mas sem profissional com dedicação exclusiva. Apenas um serviço monitora pacientes após a endoscopia, fato que dificulta a identificação dos efeitos adversos após procedimentos nessas organizações. Existem protocolos básicos de segurança do paciente na maioria dos serviços. A incidência total de efeitos adversos é 0,3%; e 0,8% para a endoscopia digestiva alta e colonoscopias. Bacteremias, dor abdominal, sangramento e perfuração intestinal são os danos mais frequentes. Todos os serviços possuem boa estrutura organofuncional para a realização dos processos de limpeza e desinfecção dos endoscópios. **Conclusão:** Os serviços possuem Núcleos de Segurança do Paciente, e implementam protocolos de segurança recomendados. Os efeitos adversos identificados estão em consonância com a literatura; entretanto, esses dados podem estar subnotificados, uma vez que esses serviços não dispõem de um sistema ativo de vigilância de eventos adversos após exames endoscópicos.

Palavras-chave: Endoscópios. Segurança do paciente. Eventos adversos.

RESUMEN: Objetivo: Analizar la incidencia de eventos adversos (EA) relacionados con los procedimientos endoscópicos gastrointestinales. **Método:** Estudio de casos múltiples en servicios ambulatorios de endoscopia digestiva tipo III (SAEG), en Salvador, BA, analizando: Centros de Seguridad del Paciente (CSP); eventos adversos y descontaminación endoscópica. **Resultados:** Participó el 28,5% de la SAEG. Hay CSP, que funcionan según Planes de Seguridad del Paciente, pero sin un profesional con dedicación exclusiva. Solo un servicio monitorea a los pacientes después de la endoscopia, hecho que dificulta la identificación de EA después de los procedimientos en estas organizaciones. En la mayoría de los servicios existen protocolos básicos de seguridad del

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paciente. La incidencia total de EA es del 0,3% y del 0,8% para endoscopias digestivas altas y colonoscopias. La bacteriemia, el dolor abdominal, el sangrado y la perforación intestinal son los daños más frecuentes. Todos los servicios cuentan con una buena estructura órgano-funcional para la limpieza y desinfección de endoscopios. **Conclusión:** Los servicios cuentan con CSP e implementan los protocolos de seguridad recomendados. Los EA identificados están en línea con la literatura, sin embargo, estos datos pueden estar subreportados, ya que estos servicios no cuentan con un sistema de vigilancia activa de eventos adversos después de los exámenes endoscópicos.

Palabras clave: Endoscopios. Seguridad del paciente. Evento adverso.

INTRODUCTION

Endoscopic procedures contribute to the prevention and treatment of several pathologies, and are especially useful for colorectal cancer screening among asymptomatic individuals. However, despite this technological advance, the use of endoscopic equipment has brought, in addition to the obvious benefits, the risk of transmission of infection greater than any other health product¹⁻⁴.

In the past, several microorganisms have been implicated in endoscope-associated infections. Recent data have revealed outbreaks of carbapenem-resistant Enterobacteriaceae and other multidrug-resistant bacteria, such as *Escherichia coli* and *Klebsiella sp.*, responsible for outbreaks that occurred in the United States between 2008 and 2015. At the time, a large number of people were affected, resulting in infections and deaths; thus, the prevention of infections after endoscopic procedures has become an important objective for patient safety¹⁻⁶.

The transmission of microorganisms related to endoscopes can occur from patient to patient, through contaminated equipment, and constitutes the most important mode of transmission. Other modes include transmission from the gastrointestinal tract to susceptible organs of the body, through the bloodstream during endoscopy, from patient to endoscopy professionals, and perhaps from professionals to patients^{4,5,7}.

Endoscopes are complex, cannulated, long devices; access mucous membranes and sterile areas of the body, and, before reuse in patients¹, require meticulous cleaning and reprocessing in strict accordance with guidelines based on scientific evidence. The reprocessing of this equipment is a multi-step process, which must ensure safety between uses, and includes, in addition to cleaning, complete immersion in a high-level disinfectant, rinsing with potable water, irrigation of the internal channels with 70% alcohol, drying, and storage¹⁻⁸.

There are reports of gaps and variation in the implementation of infection prevention practices in endoscopy

units around the world, which causes uncertainty about the possible risks for patients undergoing these procedures. Furthermore, the known data may be underestimated, as a result of the absence of an active surveillance system for endoscopy-related adverse events, with consequent under-reporting or non-recognition of these incidents. Thus, the need for an infection control system in these units is highlighted, as well as the surveillance of adverse events related to this health care^{1,4,9-15}.

Given the relevance of problems related to the use of endoscopic equipment for public health, summarized in this introduction, and in view of the scarcity of published data on adverse events in Brazilian endoscopy services, this study seeks to answer the following guiding question: what is the incidence of adverse events related to gastrointestinal endoscopic procedures? How is the endoscopic equipment processed in the services that perform these procedures?

OBJECTIVE

To analyze the incidence of adverse events related to gastrointestinal endoscopic procedures in endoscopy services in Bahia, knowing the organofunctional conditions of the Patient Safety Centers of these services and identifying the process of decontamination of endoscopic equipment carried out in the services studied.

METHOD

This study comes from a Scientific Initiation project at Universidade do Estado da Bahia (UNEB), Public Notice No. 020/2020, registered at Plataforma Brasil, CAAE Protocol No. 11666919.8.0000.0057, Opinion No. 3.274.727. This is an evaluation research whose methodological strategy is the descriptive study of multiple cases¹⁶ in endoscopy services in Bahia.

This study had the participation of gastrointestinal endoscopy services (upper digestive endoscopy and colonoscopy) classified by the National Health Surveillance Agency (*Agência Nacional de Vigilância Sanitária – ANVISA*) as “Type III”¹⁷, which work on an outpatient basis (services that work in day hospitals or in specialized clinics), located in the city of Salvador, Bahia, and selected from data from the Single Health Establishment Registry (*Cadastro Único de Estabelecimento de Saúde – CNES*).

To achieve the objectives, three analytical categories were researched:

1. Constitution of the Patient Safety Centers (*Núcleos de Segurança do Paciente – NSP*) and their organizational and functional structure (infrastructure related to human resources; responsible professional and other professionals);
2. Actions to identify adverse events in the endoscopy services studied; and
3. Technical-operational activities related to endoscopic equipment decontamination processes.

Thirty-five Type III endoscopy services were selected, and among these, only 10 (28.5%) participated in this study. The reasons for non-participation included: refusal, deactivation due to the COVID-19 pandemic, excessive bureaucracy that made access to services unavailable and unavailability of selected services for conducting research with universities.

Data collection was performed using an online Google form, prepared by the authors of the study, according to the analysis categories. Each participant signed the Informed Consent.

Each service received an e-mail with a letter addressed to the board and/or the Patient Safety Center, ratifying the research objectives and requesting the institutions’ participation. The access link to the Google survey collection form was attached in this message, accompanied by guidance on how to complete this instrument, fully online, to be answered by the professional responsible for the board and/or the Patient Safety Center and/or Technical Responsible for each endoscopy service. In addition, the project approval report by *Plataforma Brasil* was also attached to the science of the institution to be studied.

RESULTS

Table 1 characterizes the Endoscopy Services studied.

Of the ten Type III endoscopy services studied, five are privately managed, two are public, two are philanthropic, and one is public-private, described in Table 1. Of these, eight had their health licenses in force and only two had problems related to authorization to operate, such as S2 (expired health license) and S7 (no health license).

Table 1. Characterization of the studied digestive endoscopy services. Salvador; 2019.

Services studied	Expiration of the sanitary license	Sponsoring entity	NSP deployment	Monitoring of patients after endoscopic procedure
S1	12/26/2020	Private sector	11/08/2010	Not performed
S2	11/27/2018	Public sector	07/14/2015	Not performed
S3	10/08/2021	Private sector	07/20/2017	Not performed
S4	12/31/2021	Private sector	Not informed	Not performed
S5	02/17/2021	Private sector	02/01/2018	Patients receive an information form containing telephone contact to notify any occurrence.
S6	09/29/2021	Private sector	01/01/2016	Patients receive an information form containing telephone contact to notify any occurrence.
S7	Não possui alvará.	Public sector	08/09/2018	Patients receive an information form containing telephone contact to notify any occurrence.
S8	06/06/2021	Public-private sector	01/02/2014	Not performed.
S9	01/04/2022	Philanthropic	04/15/2013	Not performed
S10	03/12/2022	Philanthropic	10/27/2017	Patients receive an information form, the service contacts all patients in order to investigate AE and records this data.

NSP: patient safety centers (*núcleo de segurança do paciente*); AE: adverse effects.

There are Patient Safety Centers (*Núcleos de Segurança do Paciente – NSP*) in nine services, implemented between 2010 and 2018.

The follow-up of patients after endoscopic procedures is carried out by only one service (S10), and in four of them (S5, S6, S7, and S10), patients receive an information leaflet containing the telephone contact for notification of any complaint or symptom following the exam.

The organofunctional structure of the NSP of the endoscopy services is described in Chart 1.

Of the ten endoscopy services, six have an autonomous organizational structure and seven have formally constituted NSPs. Among the professionals who work in the NSP of these services, the nurse is part of all the centers; doctors and pharmacists constitute a large majority; most professionals have specialized technical training.

The existence of a responsible professional with exclusive dedication to the NSP was identified in only four services (S3, S6, S7, and S9). Planning with specific goals for the control of adverse events was identified in nine services.

Chart 1. Organo-functional structure of the patient safety centers of the studied endoscopy services. Salvador; 2019.

Services studied	Formally constituted NSP	Composition of NSPs of endoscopy services	NSP organizational structure	Technical training of NSP professionals	Professional with exclusive dedication	Existence of patient safety plans	Basic security protocols developed by the NSP
S1	Yes	Nurse; Physician; Pharmacist; Administrator; Occupational Safety Technician; Psychologist.	Autonomous	Courses, Specializations and Doctorate	No	Yes	1. Patient identification; 2. Prevention of falls; 3. Prevention of medication errors; 4. Hand hygiene; 5. Effective communication.
S2	Yes	Nurse; Physician; Pharmacist; Administrator; User representatives; Residents of medical and multiprofessional residency.	Autonomous	Face-to-face and non-face-to-face courses and Specializations	No	Yes	1. Patient identification; 2. Prevention of falls; 3. Pressure ulcer prevention; 4. Prevention of medication errors; 5. Hand hygiene; 6. Communication; 7. Invasive procedures.
S3	No	Not informed	Not informed	Face-to-face and non-face-to-face courses	Yes	Yes	1. Patient identification; 2. Prevention of falls; 3. Prevention of medication errors; 4. Hand hygiene.
S4	No	Not informed	Not informed	Not informed	Not informed	Not informed	Not informed
S5	No	Not informed	Inserted in another service.	Specializations	No	Yes	1. Protocol for patient identification.
S6	Yes	Nurse; Physician; Pharmacist.	Autonomous	Specializations	Yes	Yes	1. Protocol for patient identification; 2. Prevention of falls; 3. Error prevention and, medication; 4. Hand hygiene.

Continue..

Chart 1. Continuation.

Services studied	Formally constituted NSP	Composition of NSPs of endoscopy services	NSP organizational structure	Technical training of NSP professionals	Professional with exclusive dedication	Existence of patient safety plans	Basic security protocols developed by the NSP
S7	Yes	Nurse; Physician; Pharmacist; Physiotherapist; Nutrologist; Nutritionist; Psychologist; Social worker; Biochemist; Information Technology; Clinical engineering.	Inserted in another service.	Face-to-face and non-face-to-face courses; Specializations.	Yes	Yes	1. Patient identification; 2. Prevention of falls; 3. Prevention of medication errors; 4. Hand hygiene; 5. Bronchoaspiration protocol; 6. Assistance to Emergency patients; 7. Anesthesiologist support.
S8	Yes	Nurse; Physician; Pharmacist; Psychologist.	Autonomous	Face-to-face and non-face-to-face courses; Specializations; Master's degree.	No	Yes	1. Patient identification; 2. Prevention of falls; 3. Pressure ulcer prevention; 4. Prevenção de erros em medicamentos; 5. Hand hygiene.
S9	Yes	Nurse.	Autonomous	Specializations.	Yes	Yes	1. Patient identification; 2. Prevention of falls; 3. Pressure ulcer prevention; 4. Prevention of medication errors; 5. Hand hygiene.
S10	Yes	Nurse; Physician; Pharmacist; Physiotherapist.	Autonomous	Face-to-face and non-face-to-face courses; Specializations; Master's degree; Doctorate degree.	No	Yes	1. Patient identification; 2. Prevention of falls; 3. Prevention of medication errors; 4. Hand hygiene.

NSP: Patient Safety Centers (*núcleo de segurança do paciente*).

Of the six basic patient safety protocols recommended by the Ministry of Health (Patient identification; Safe surgery; Hand hygiene; Prevention of falls and pressure ulcers; Prevention of medication errors; Effective communication), most services develop them all, except for S4, which did not inform whether they are developed, and S5, which only implements the patient identification protocol.

Table 2 shows that, in 2019, the endoscopy services studied performed 29,884 upper gastrointestinal endoscopy (UGE) procedures and 14,717 colonoscopies, with a total mean incidence of adverse effects (AE) of 0.3 and 0.8% for the exams of UGE and colonoscopy, respectively.

The overall incidence of AE related to UGE by service ranged from 0.08% (S1) to 3.57% (S5); in relation to colonoscopy, there was a variation of AE from 0.44% (S1) to 7.14% (S5).

Table 2. Occurrence of adverse events in upper digestive endoscopies and colonoscopies in the endoscopy services studied. Salvador; 2019.

Services studied	Total UGE	Total colonoscopy	AE in UGE (%)	AE in colonoscopy (%)	Total AE incidence (%)
S1	12,345	6,685	Bacteremias 10/12,345 (0.08)	Bacteremias (10–0.14); Colon perforation (10–0.14); Bleeding (10–0.14) 30/6,685 (0.44)	40/19,030 (0.21)
S2	1,233	301	Abdominal pain (10–0.8); Bleeding (10–0.8). 20/1,233 (1.62)	Abdominal pain (10–3.32), 10/301 (3.32)	30/1,534 (1.95)
S3	3,901	2,587	Abdominal pain (10–0.2); Bleeding (10–0.2). 20/3,901 (0.51)	Abdominal pain (10–0.4); Bleeding (10–0.4). 20/2,587 (0.77)	40/6,488 (0.61)
S4	400	200	0	Others (10–5) 10/200 (5)	10/600 (1.66)
S5	280	140	Abdominal pain (10–3.6) 10/280 (3.6)	Abdominal pain (10–7.1) 10/140 (7.1)	20/420 (4.76)
S6	3,899	2,407	0	Abdominal pain (20–0.8) 20/2,407 (0.83)	20/6,306 (0.31)
S7	4,823	1,021	0	0	-
S8	2,335	166	0	0	-
S9	873	475	0	0	-
S10	668	735	Abdominal pain (10–1.5); Bleeding (10–1.5). 20/668 (2.99)	Abdominal pain (10–1.3); Bleeding (10–1.3). 20/735 (2.72)	40/1,403 (2.85)
Total	29,884	14,717	80 (0.3)	120 (0.8)	

UGE: Upper gastrointestinal endoscopy; AE: adverse effect.

In the services studied, the most incident AEs related to UGE were: bacteremia (0.03%), abdominal pain (0.13%), and bleeding (0.1%). For colonoscopies, bacteremia (0.06%), abdominal pain (0.34%), bleeding (0.2%), and intestinal perforation (0.06%) were also identified as the most frequent damages.

According to Chart 2, all services have a cleaning and disinfection room, with adequate equipment washing tank and auxiliary bench, as well as the use of good quality water in the endoscope decontamination processes. The air conditioning system does not meet the regulations in four services (S1, 2, 6, and 8). There are standard operating procedures and pre-cleaning of endoscopes immediately after examination in all facilities.

The services studied have adequate cleaning processes, the detergents used are registered by ANVISA and are diluted and discarded as recommended by the manufacturer. Regarding the artifacts used to clean the endoscopes, the services perform cleaning and disinfection of them, as recommended.

Complex products undergo manual cleaning prior to ultrasonic cleaning. The rinsing and drying processes after cleaning are adequate in all services.

As described in Chart 3, all services perform high-level disinfection of gastrointestinal endoscopes, as well as adequate rinsing and drying after this process. However, in two services (S2 and S8), there is no daily monitoring of the biocidal activity of the germicidal solution. The routine of applying 70% alcohol in the internal channels of the devices after drying was identified in all services. Critical products, such as biopsy forceps and papillotomes, are sterilized in the ten services studied.

During the processing of endoscopes, professionals wear PPE as recommended. The storage conditions of endoscopes after the exams are finished are adequate, as well as the containers that transport this equipment.

DISCUSSION

Data from this study portray 28.5% of Type III gastrointestinal endoscopy services located in Salvador, with different management systems.

Chart 2. Physical-functional structure of the cleaning processes of the endoscopic equipment of the endoscopy services studied. Salvador; 2019.

Structure of services	S1	S2	S3	S4	S5	S6	S7	S8	S9	S10
Existence of cleaning and disinfection room	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Suitability of the cleaning tub	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Presence of assistance bench	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Adequacy of water quality	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Adequacy of the air conditioning system	No	No	Yes	Yes	Yes	No	Yes	No	Yes	Yes
Existence of SOPs	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Endoscope pre-cleaning in the exam room	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Adequacy of cleaning processes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Detergent registered with ANVISA	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Adequacy of detergent dilution and disposal	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Change after every wash	Yes	Yes
Cleaning/disinfection of cleaning artifacts	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Manual cleaning preceded by ultrasonic cleaning of complex products	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Proper rinse	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Proper drying	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

SOPs: standard operating procedure.

Chart 3. Physical-functional structure of the disinfection and sterilization processes of the endoscopic equipment of the studied endoscopy services. Salvador; 2019.

Structure of services	S1	S2	S3	S4	S5	S6	S7	S8	S9	S10
High-level disinfection of endoscopes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Monitoring of the biocidal activity of the disinfectant	Yes	No	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes
Proper rinse	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Proper drying	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Application of 70% alcohol in the canals	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Proper storage	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Sterilization of critical articles	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Adequacy of the use of PPE	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Suitability of containers that carry endoscopes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

PPE: personal protective equipment.

Most of these organizations have health licenses in place. However, it was found that, in a private management service, this license was expired, and in another public management service, there was no health license, which points to inadequacies in the sphere of health control of these institutions.

In order to function, health services need a health license, granted by the Health Surveillance Department if they meet the requirements established in the health regulations. This license, to be renewed annually, indicates that, at that

moment, the establishment meets the health requirements for its operation. Thus, two of the endoscopy services studied have health infractions related to the operating permit.

NSPs were implemented between 2010 and 2018, with the exception of one service, without a NSP, in disagreement with the Resolution of the Collegiate Board (*Resolução da Diretoria Colegiada – RDC*) No. 36/2013¹⁸ of ANVISA, which obliges all health services in the country to set up NSPs to deal with adverse events resulting from health care.

These NSPs are formally constituted in most services, have an autonomous organizational structure and work with Patient Safety Plans (PSP). Among the professionals who work in these centers, nurses are part of all the centers. However, the existence of a responsible professional with exclusive dedication to the NSP, as recommended by the regulations, was identified in only four services, contrary to the regulatory framework and limiting the performance in favor of patient safety in the institutions studied.

Epidemiological surveillance of adverse events related to endoscopic procedures is an important strategy for the quality of the procedure and patient safety. Systematic monitoring makes it possible to know the data manifested after examinations and the possibility of adopting measures to prevent and control these diseases^{10,16,19}. However, in most endoscopy services, as confirmed in this study, this surveillance is absent or passive, receiving information from patients or endoscopists, which contributes to the underreporting of adverse events related to endoscopies.

Most endoscopy services adopt all basic patient safety protocols recommended by the Ministry of Health. The exceptions were a service that did not report this data and a service that only implements the patient identification protocol. These protocols are construction instruments for a safe care practice and should be part of the mandatory components of patient safety plans.

For the American Society for Gastrointestinal Endoscopy, adverse events related to gastrointestinal endoscopy are rare and include infection, perforation, and bleeding. The incidence of bacteremia after upper endoscopy is less than 8%, and ranges from 0 to 53% after esophageal sclerosis, from 1 to 25% after ligation of varices, and from 2 to 54% after esophageal dilation. The incidence of bacteremia after colonoscopy ranges from 0 to 25% and, after sigmoidoscopy, it ranges from 0 to 1%^{7,20,21}.

In this study, we identified a mean AE incidence of 0.3 and 0.8% for UGE and colonoscopy exams, respectively. Apparently, the indices are within the previously reported data. However, these data originate from reports made by patients and by endoscopists, perhaps not representing the totality of adverse events manifested after examinations.

For colonoscopic examinations, a meta-analysis consisting of 21 studies published between 2001 and 2015 estimated incidences of perforation, bleeding, and mortality in the proportions of 0.5/1000, 2.6/1000, and 2.9/100 000 procedures⁶.

These data were also visualized in this study, in which bacteremia (0.03%), abdominal pain (0.13%), and bleeding

(0.1%) were the most incident UGE-related adverse effects. For colonoscopies, bacteremia (0.06%), abdominal pain (0.34%), bleeding (0.2%), and intestinal perforation (0.06%) were also identified as the most frequent damage, indicators below the data previously mentioned.

Among the services studied, two stand out: S1, with the highest number of procedures performed and the lowest AE identified; and S5, with the lowest number of tests and the highest indicators of AE, demonstrating, in this study, how these services differ in matters related to the safety of patients undergoing these procedures and pointing out the inevitable need for prior evaluation of these services by users, when it is necessary to undergo an endoscopic procedure.

The services have a good organofunctional structure to carry out the cleaning and disinfection processes of endoscopes. All of them have an exclusive cleaning and disinfection room, with adequate equipment washing tank and support bench, as well as good quality of the water used in the endoscope decontamination processes, as recommended by RDC ANVISA No. 06/2013¹⁷. However, the room's air conditioning system does not meet this regulation in four services, contributing to possible occupational problems for health professionals who work with endoscope decontamination activities.

There are standard operating procedures to clean and disinfect endoscopic equipment, denoting planning actions for the decontamination processes of these devices in these services. The pre-cleaning of endoscopes immediately after the examination is performed in all services, in line with the recommendations in the literature, which recommend the beginning of cleaning procedures still inside the examination rooms, to prevent the drying of secretions in the internal channels of these devices and the onset of biofilms^{22,23}.

The services studied have adequate cleaning processes; the detergents used are registered by ANVISA and are diluted and discarded as recommended by the manufacturer. Regarding the artifacts used to clean the endoscopes, the services perform their cleaning and disinfection as recommended by the literature.

Complex products are subjected to manual cleaning prior to ultrasonic cleaning, according to ANVISA RDC 06/2013¹⁷. The rinsing and drying processes after cleaning are suitable for all services.

Endoscopes undergo high-level disinfection, as recommended by the literature, as well as rinsing, drying, and appropriate controls after this process. However, two services do not perform daily monitoring of the biocidal activity

of the germicidal solution, configuring a sanitary infraction and bad practice when using chemical disinfectant solutions, given the imperative need for knowledge, on the part of the health services, of the microbiocidal capacity of the germicidal product in use. The routine of application of 70% alcohol in the internal channels of the devices after drying, recommended to facilitate the internal drying of the endoscopic channels and to enhance the disinfection process, was identified in all services.

Critical products, such as biopsy forceps and papillotomes, are sterilized in the ten services studied, indicating adjustments regarding the method of decontamination of devices that access sterile areas of the body.

When processing endoscopes, practitioners wear appropriate PPE, as recommended. Storage conditions of endoscopes after the end of the exams are adequate, as well as the containers that transport this equipment.

CONCLUSION

This study achieved its objective by analyzing adverse events related to gastrointestinal endoscopic procedures in endoscopy services in Bahia, evaluating the conditions that provide safety to the assisted patients.

We consider as a limitation the fact that we contemplated only 28.5% of the Type III gastrointestinal endoscopy services, which certainly does not represent the totality of them and does not allow statistical generalizations.

Despite this limitation, our data contribute to the advancement of knowledge about patient safety in gastrointestinal endoscopy services in the country's 4th largest city in

population, pointing out the need for greater control through Health Surveillance in order to comply with regulations laws in effect for some of these services.

The types and incidence of adverse events identified in this study are in line with those reported in the literature. However, these data may be underreported, since these services do not have an active surveillance system for adverse events after examinations, a fact that makes it difficult to identify related damages.

Endoscopy services differ in issues related to patient safety, signaling the inevitable prior assessment of these organizations, by users, when the need to undergo an endoscopic procedure is necessary.

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None.

CONFLICT OF INTERESTS

The authors declare there is no conflict of interests.

AUTHORS' CONTRIBUTION

EAMC: Formal analysis, Conceptualization, Writing — original draft, Writing — review & editing. **JB:** Formal analysis, Conceptualization, Writing — original draft, Writing — review & editing. **RA:** Formal analysis, Conceptualization, Writing — original draft, Writing — review & editing.

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